



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA-HQ-OPPT-2021-0622; FRL-9100-01-OCSPP]

TSCA Section 21 Petition for Rulemaking under TSCA Section 6; Reasons for Agency Response; Denial of Requested Rulemaking

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: This action announces the availability of EPA’s response to a petition received on August 16, 2021, from William D. Bush. The petition requests that EPA determine that the “chemical mixtures contained within cosmetics present an unreasonable risk of injury to health and the environment,” and issue a rule or order under the Toxic Substances Control Act (TSCA) to “eliminate the hazardous chemicals used in mixtures [in cosmetics].” After careful consideration, EPA has denied the petition for the reasons set forth in this document.

DATES: EPA’s response to this TSCA section 21 petition was signed November 10, 2021.

ADDRESSES: The docket for this petition, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0622, is available at <https://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Public Reading Room is by appointment only. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Amy

Shuman, Existing Chemicals Risk Management Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-2978; email address: *shuman.amy@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those persons who manufacture (including import), distribute in commerce, process, use, or dispose of cosmetics. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8, or to issue an order under TSCA sections 4, 5(e), or 5(f). A TSCA section 21 petition must set forth the facts which it is claimed establish that it is necessary to initiate the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the *Federal Register*. A petitioner may commence a civil action in a U.S. district court seeking to compel initiation of the requested proceeding within 60 days of a denial or, if EPA does not issue a decision, within 60 days of the expiration of the 90-day period.

C. What criteria apply to a decision on this TSCA section 21 petition?

1. Legal standard regarding TSCA section 21 petitions.

TSCA section 21(b)(1) requires that the petition “set forth the facts which it is claimed establish that it is necessary” to initiate the proceeding requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. Accordingly, EPA has relied on the standards in TSCA section 21 and in the provisions under which actions have been requested in evaluating this TSCA section 21 petition.

2. Legal standard regarding TSCA section 6(a).

In general, to promulgate a rule under TSCA section 6(a), EPA must first determine “in accordance with section 6(b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents an unreasonable risk.” 15 U.S.C. 2605(a). TSCA section (b)(4)(A) is part of the risk evaluation process whereby EPA must determine “whether a chemical substance presents an unreasonable risk of injury to health or the environment,” and thus, whether a rule under TSCA section 6(a) is necessary. 15 U.S.C. 2605(b)(4)(A). In particular, EPA must conduct this evaluation “without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.” *Id.* Unless EPA establishes an exemption under TSCA section 6(g) (whereby certain unreasonable risks may be allowed to persist for a limited period) or EPA is addressing a persistent, bioaccumulative, and toxic substance as set forth in TSCA section 6(h), the standard for an adequate rule under TSCA section 6(a) is that it regulates “so that the chemical substance or mixture no longer presents” unreasonable risks under the conditions of use. 15 U.S.C. 2605(a). EPA may eliminate the unreasonable risk of a chemical substance or mixture by regulating manufacture, processing, distribution in commerce, commercial use, or disposal of the chemical substance in one or more of the manners described in TSCA section 6(a).

3. Legal standard regarding TSCA sections 3(2) and (10).

TSCA section 3(2) excludes from the definition of a “chemical substance” “any food, food additive, drug, *cosmetic*, or device (as such terms are defined in Section 201 of the Federal

Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, *cosmetic*, or device.” 15 U.S.C. 2602(2) (emphases added). In addition, TSCA section 3(10) defines “mixture” as “any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.” 15 U.S.C. 2602(10).

4. Legal standard regarding TSCA section 26.

TSCA section 26(h) requires EPA, in carrying out TSCA sections 4, 5, and 6, to make science-based decisions using “scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science,” while also taking into account other considerations, including the relevance of information and any uncertainties. 15 U.S.C. 2625(h). TSCA section 26(i) requires that decisions under TSCA sections 4, 5, and 6 be “based on the weight of scientific evidence.” 15 U.S.C. 2625(i). TSCA section 26(k) requires that EPA consider information that is reasonably available in carrying out TSCA sections 4, 5, and 6. 15 U.S.C. 2625(k).

II. Summary of the TSCA Section 21 Petition

A. What action was requested?

On August 16, 2021, EPA received a TSCA section 21 petition (Ref. 1) from William D. Bush (the petitioner) that requests EPA take several actions under TSCA section 6. The petition asks EPA to determine that the “chemical mixtures contained within cosmetics present an unreasonable risk of injury to health and the environment” and seeks the issuance of a rule or order to “eliminate the hazardous chemicals used in mixtures [in cosmetics].” The petition also requests “any other prudent [methods] of toxic mixture substance control [EPA] may see due and

fit.”

1. Request for determination that the chemical mixtures contained within cosmetics present an unreasonable risk of injury to health and the environment.

The petition requests that EPA determine that the “chemical mixtures contained within cosmetics present an unreasonable risk of injury to health and the environment.” With respect to actions under TSCA section 6, TSCA section 21 provides only for the submission of a petition seeking the initiation of a proceeding for the issuance, amendment, or repeal of a rule under TSCA section 6(a). In general, before promulgating a TSCA section 6(a) rule, EPA must first determine “in accordance with section 6(b)(4)(A)” – that is, through a TSCA risk evaluation – whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use. To initiate a TSCA section 6(b) risk evaluation, however, EPA generally must designate the chemical substance a high priority for risk evaluation. Prioritization of high priority substances for risk evaluation under TSCA section 6(b) and risk evaluation under TSCA section 6(b) are activities distinct from rulemaking under TSCA section 6(a). Because TSCA section 21 does not provide an avenue for petitioners to request the initiation of the prioritization process or the risk evaluation process through which EPA would determine whether “chemical mixtures contained within cosmetics” present an unreasonable risk, this Federal Register document does not address this specific request.

2. Request for order by rule that the manufacturing producers of cosmetics eliminate the hazardous chemicals used in mixtures in cosmetics.

The petition requests that EPA “[o]rder by [r]ule that the manufacturing producers of cosmetics eliminate the hazardous chemicals used in mixtures [in cosmetics].” TSCA section 21 provides for the submission of a petition to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8, or to issue an order under TSCA sections 4, 5(e), or 5(f). As the petitioner is seeking issuance of a rule under TSCA section 6, this Federal Register document addresses this request.

3. Request for other methods of toxic mixture substance control the agency determines to be required.

The petition requests that EPA exercise “any other prudent [methods] of toxic mixture substance control” that the Agency deems “due and fit.” As a regulatory body, EPA cannot deviate from the statutory remedies established under TSCA section 21. Therefore, a solicitation for EPA to exercise “any other prudent [methods]” that the Agency deems “due and fit” does not adequately identify an objective that is executable within TSCA section 21. Therefore, this Federal Register document does not address this specific request.

B. What support did the petitioner offer?

To support the request for an order by rule that the manufacturing producers of cosmetics eliminate the hazardous chemicals used in mixtures in cosmetics, the petitioner offers information relating to human health impacts as a result of cosmetic application, human health and environmental impacts affected by cosmetic manufacture and import volume, and lack of cosmetic regulatory policy (Ref. 1, pp. 1-4). Of 13 points included in that discussion, seven are excerpts from an article on the toxicity of chemicals and contaminants of cosmetics (Ref. 2); these points are discussed in detail below. For the remaining six points, the petitioner paraphrases information from the article (Ref. 2), and references the authority of the U.S. Food and Drug Administration and regulatory actions taken worldwide as each relates to human health and environmental impacts from cosmetic chemicals.

Regarding the seven points attributed to the article on the toxicity of chemicals and contaminants in cosmetics, the petitioner cites various metrics associated with the manufacture and use of cosmetic products (Ref. 1, points 5, 10, 11, and 12) and the alleged environmental and human health effects resulting from exposure thereto (Ref. 1, points 1, 5, and 10).

Regarding manufacturing metrics, the petitioner highlights references from the article by stating, “[s]ince 2009, 595 cosmetic manufacturers reported using 88 chemicals, in more than 73,000 [cosmetic] products” (Ref. 1, point 5). The petitioner further states that “American

women use an average of 12 personal care products that contain 168 different chemicals” and that the United States cosmetic industry since 2010 “has grown an average of 4.1 percent annually” with sales from 2016 totaling over \$169 billion (Ref. 1, points 10 and 11). Lastly, the petitioner points to increased import of cosmetics from 181 different countries by highlighting “[c]osmetic imports from China increased 79 percent between FY 2011 and FY 2016” (Ref. 1, point 12).

The associated health affects statements mentioned by the petitioner include that cosmetic chemicals “have been linked to cancer, birth defects, and reproductive harm” and that “[m]any of these products are applied directly to the skin, the body’s largest organ, where ingredients can be absorbed directly into the bloodstream” (Ref. 1, points 5 and 10). To expand on this point, the petitioner states “[n]ot only are these toxic chemicals entering our bodies through direct application, but excess product that is washed down the drain pollutes our waterways and drinking water, and compounds doses of hazardous chemicals in air, water, food, and other consumer products” (Ref. 1, point 1).

In addition, the petitioner includes a summary of the findings and policy section of the Pollution Prevention Act (42 U.S.C. 13101) (Ref. 1, points 14 and 15), though TSCA section 21 does not provide an avenue for recourse under such Act. The petitioner cites language from the Pollution Prevention Act which states that “pollution should be prevented or reduced at the source whenever feasible; pollution that cannot be prevented should be recycled in an environmentally safe manner, whenever feasible; pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner” and that “source reduction is fundamentally different and more desirable than waste management and pollution control.”

The petitioner also provides two claims: (1) “[t]oxic [c]hemicals added to and included in [c]osmetics are unreasonable;” and (2) “[c]osmetic [d]isposal presents a clear unreasonable risk

to the [e]nvironment.” (Ref. 1, pp. 5-6). To support the former claim, the petitioner argues that the chemical mixtures contained in cosmetics provide no benefit to consumers considering said chemicals can “harm public welfare and the environment through their use consumption and disposal,” but does not cite or provide reference. To support the latter claim, the petitioner states that “research studies of toxic waste entering the environment are clear in identifying cosmetics as a major hazardous waste emission,” but does not cite or provide any reference to such studies.

III. Disposition of TSCA Section 21 Petition

A. What is EPA’s response?

After careful consideration, EPA has denied this TSCA section 21 petition. A copy of the Agency’s response, which consists of the letter to the petitioner and this document, is posted on the EPA petition website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsc/tsc-section-21#cosmetics>. The response, the petition (Ref. 1), and other information is available in the docket for this TSCA section 21 petition.

B. What was EPA’s reason for this response?

TSCA section 21 does provide for the submission of a petition seeking the initiation of a proceeding for the issuance of a rule under TSCA section 6(a). The petition must “set forth the facts which it is claimed establish that it is necessary to issue” the requested rule. 15 U.S.C. 2620(b)(1). When determining whether the petition meets that burden, EPA will consider whether the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or any combination of such activities, may present an unreasonable risk of injury to health or the environment.

EPA evaluated the information presented in the petition and considered that information in the context of the applicable authorities and requirements of TSCA sections 3(2), 6, 21, and 26. Notwithstanding that the burden is on the petitioner to present “the facts which it is claimed establish that it is necessary” for EPA to initiate the rule or issue the order sought, EPA nonetheless also considered relevant information that was reasonably available to the Agency

during the 90-day petition review period. As detailed further in this Unit, EPA finds that the petitioner has not met its burden to support the requested actions.

Under TSCA section 6(a), EPA must, by rule, issue regulations applying one or more of the listed requirements to the extent necessary so that a chemical substance or mixture found to present unreasonable risk no longer presents such risk.—TSCA section 3(2)(B), which defines “chemical substance,” excludes “any food, food additive, drug, *cosmetic*, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, *cosmetic*, or device” (emphases added). According to section 201(i) of the Federal Food, Drug, and Cosmetic Act (FFDCA), “cosmetic” means “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles; except that such term shall not include soap.” 21 U.S.C. 321(i). Under TSCA, “cosmetics” are not a “chemical substance” when manufactured, processed, or distributed in commerce for use as a cosmetic. Therefore, EPA cannot issue a rule pursuant to TSCA section 6(a) to apply requirements to such cosmetics. In addition, while a “mixture” can be subject to TSCA section 6(a), because the requested action is for “hazardous chemicals used in mixtures [in cosmetics],” EPA cannot issue a rule pursuant to TSCA section 6(a) to apply requirements to cosmetics when manufactured, processed, or distributed in commerce for use as a cosmetic. To the extent the petition seeks action on “cosmetics” when manufactured, processed, or distributed in commerce as cosmetics – including direct regulation of cosmetics through an order by rule that cosmetic manufacturers eliminate hazardous chemicals used in mixtures in cosmetics or through an action to address the first claim that “[t]oxic [c]hemicals added to and included in [c]osmetics are unreasonable” – the petition does not request actions that are within EPA’s jurisdiction under TSCA.

To the extent the petition seeks action on “chemical substances” within the TSCA section

3(2) definition of that term – including action to address the petitioner’s second claim that “[c]osmetic [d]isposal presents a clear unreasonable risk to the [e]nvironment” – EPA finds that the petitioner did not set forth facts establishing that it is necessary to initiate an appropriate proceeding pursuant to TSCA section 21. In particular, with respect to the second claim, EPA finds that the petition did not demonstrate facts that could support an EPA determination of unreasonable risk to the environment. Rather, the specific chemical substances identified by the petition as examples are discussed by reference to their potential human health effects when used in manufactured cosmetic products. In addition, while the petition cites TSCA and Pollution Prevention Act authorities applicable to disposal, there are no data or references offered to support the assertion that “research studies of toxic waste entering the environment are clear in identifying cosmetics as a major hazardous waste emission” (Ref. 1, p. 6). As explained above, TSCA section 21(b)(1) requires that the petition “set forth the facts which it is claimed establish that it is necessary” to initiate the proceeding requested. 15 U.S.C. 2620(b)(1). TSCA section 21(b)(4)(B) also provides the standard for judicial review should EPA deny a request for rulemaking under TSCA section 6(a): “If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that . . . the chemical substance or mixture to be subject to such rule . . . presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use,” the court shall order the EPA Administrator to initiate the requested action. 15 U.S.C. 2620(b)(4)(B). Consistent with these provisions, a petition for a TSCA section 6(a) rulemaking must set forth facts which would enable EPA to conclude that there is an unreasonable risk for which a TSCA section 6(a) risk management rule is warranted. EPA does not find that the petition in this case sets forth facts which would enable EPA to conclude that the disposal of particular chemical substance(s) or mixture(s) in cosmetics presents unreasonable risk and that an appropriate proceeding should be initiated. To the extent the petition seeks other action cognizable under TSCA section 21 to

address “chemical substances” in cosmetics outside of cosmetic disposal, EPA similarly finds that the petition does not set forth sufficient facts to establish the necessity of initiating an appropriate proceeding under TSCA section 21.

Finally, to the extent that the petition referenced the Pollution Prevention Act (42 U.S.C. 13101), the Agency reiterates that TSCA section 21 does not provide an avenue for recourse under such Act.

B. What were EPA’s conclusions?

EPA denied the request to issue a rule under TSCA section 6(a). TSCA section 3(2)(B) excludes “cosmetic” from the definition of “chemical substance” when manufactured, processed, or distributed in commerce for use as a cosmetic. Therefore, cosmetics, and any combination of chemicals contained therein, are not chemical substances under TSCA when manufactured, processed, or distributed in commerce for use as a cosmetic. To the extent the petition seeks TSCA section 6 action on “cosmetics” when manufactured, processed, or distributed in commerce as cosmetics, the requested actions are not within EPA’s jurisdiction under TSCA. In addition, to the extent the petition seeks action on “chemical substances” within the TSCA section 3(2) definition of that term, EPA finds that the petition did not set forth facts establishing that it is necessary to initiate an appropriate proceeding pursuant to TSCA section 21. In particular, the petition did not identify the disposal of any particular chemical substance(s) or mixture(s) that could support an EPA determination of unreasonable risk to the environment and, therefore, did not set forth sufficient facts establishing that it is necessary to issue a TSCA section 6(a) rule addressing cosmetic disposal.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating

these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. Bush, William D. Petition for Issuance of New Rules under Section 15 U.S.C. 2605 re: [COSMETICS]. Received August 16, 2021.

2. Faber, S. (2020). The Toxic Twelve Chemicals and Contaminants in Cosmetics. Available at <https://www.ewg.org/the-toxic-twelve-chemicals-and-contaminants-in-cosmetics>.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: November 10, 2021.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2021-25027 Filed: 11/16/2021 8:45 am; Publication Date: 11/17/2021]